

AMENDMENTS TO THE CLAIMS

*Listing of Claims:*

1. (Currently Amended) A pharmaceutically acceptable oral formulation comprising core material which comprises a therapeutically effective amount of a 5-HT-receptor agonist, or a pharmaceutically acceptable salt, solvate or derivative thereof, which core material is provided with a substantially water resistant coating comprising one or more substantially water resistant materials, wherein said one or more substantially water resistant materials comprise one or more waxes, or one or more wax derivatives.

2. (Original) A pharmaceutically acceptable oral formulation according to claim 1, wherein said 5-HT-receptor agonist is selected from the group consisting of sumatriptan, zolmitriptan, naratriptan and rizatriptan, and pharmaceutically acceptable salts, solvates and derivatives thereof.

3. (Original) A pharmaceutically acceptable oral formulation according to claim 2, wherein said 5-HT-receptor agonist is sumatriptan, or a pharmaceutically acceptable salt or solvate thereof.

4. (Currently Amended) A pharmaceutically acceptable oral formulation according to ~~claim 4~~ claim 3, wherein said 5-HT-receptor agonist is sumatriptan succinate.

5. (Currently Amended) A pharmaceutically acceptable oral formulation according to any of ~~claims 1 to 4~~ claim 1, which is substantially free of degradation products associated with exposure of a 5-HT-receptor agonist to ambient moisture.

6. (Currently Amended) A pharmaceutically acceptable oral formulation according to ~~claims 4 and 5~~ claim 4, which is a tablet formulation including 25mg of sumatriptan succinate, and wherein there is present under storage conditions of about 1 month at 25EC and 60% relative humidity, less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

7. (Original) A pharmaceutically acceptable oral formulation according to claim 6, wherein there is present under storage conditions of about 1 month at 25EC and 60% relative humidity, less than about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

8. (Original) A pharmaceutically acceptable oral formulation according to claim 7, wherein there is present under storage conditions of about 1 month at 25EC and 60% relative humidity, about 0.50% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

9. (Currently Amended) A pharmaceutically acceptable oral formulation according to ~~claims 4 and 5~~ claim 4, which is a tablet formulation including 25mg of sumatriptan succinate, and wherein there is present under storage conditions of about 1 month at 40EC and 75% relative humidity, less than about 0.65% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

10. (Original) A pharmaceutically acceptable oral formulation according to claim 9, wherein there is present under storage conditions of about 1 month at 40EC and 75% relative humidity, less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

11. (Original) A pharmaceutically acceptable oral formulation according to claim 10, wherein there is present under storage conditions of about 1 month at 40EC and 75% relative humidity, about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

12. (Currently Amended) A pharmaceutically acceptable oral formulation according to ~~claims 4 and 5~~ claim 4, which is a tablet formulation including 100mg of sumatriptan succinate, and wherein there is present under storage conditions of about 1 month at 25EC and 60% relative humidity, less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

13. (Original) A pharmaceutically acceptable oral formulation according to claim 12, wherein there is present under storage conditions of about 1 month at 25EC and 60% relative humidity, less than about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

14. (Original) A pharmaceutically acceptable oral formulation according to claim 13, wherein there is present under storage conditions of about 1 month at 25EC and 60% relative humidity, about 0.50% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

15. (Currently Amended) A pharmaceutically acceptable oral formulation according to ~~claims 4 and 5~~ claim 4, which is a tablet formulation including 100mg of sumatriptan succinate, and wherein there is present under storage conditions of about 1 month at 40EC and 75% relative humidity, less than about 0.65% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

16. (Original) A pharmaceutically acceptable oral formulation according to claim 15, wherein there is present under storage conditions of about 1 month at 40EC and 75% relative humidity, less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

17. (Original) A pharmaceutically acceptable oral formulation according to claim 16, wherein there is present under storage conditions of about 1 month at 40EC and 75% relative humidity, about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

18-30. (Canceled)

31. (Currently Amended) A formulation according to ~~any of claims 18 to 30~~ claim 1, wherein said wax is selected from the group consisting of beeswax, shellac, carnauba wax, spermaceti, lanolin, jojoba oil, candellila wax, ozocerite and opaglos 6000 P.

32. (Original) A formulation according to claim 31, wherein said wax is selected from the group consisting of carnauba wax, beeswax and opaglos 6000 P.

33. (Currently Amended) A formulation according to ~~any of claims 1 to 32~~ claim 1, wherein said substantially water-resistant coating further comprises one or more coating excipient materials, solvents for the waxes and plasticizers to coat solid formulations.

34. (Currently Amended) A formulation according to ~~any of claims 1 to 33~~ claim 1, wherein said substantially water-resistant coating is directly applied to the core material.

35. (Currently Amended) A formulation according to ~~any of claims 1 to 34~~ claim 1, wherein core material comprises sumatriptan succinate, mannitol or dibasic calcium phosphate or calcium

carbonate, hypromellose and / or microcrystalline cellulose, croscarmellose sodium and magnesium stearate.

36. (Original) A formulation according to claim 35, wherein core material comprises sumatriptan succinate, mannitol, hypromellose and / or microcrystalline cellulose, croscarmellose sodium and magnesium stearate.

37. (Original) A formulation according to claim 35, wherein core material comprises sumatriptan succinate, dibasic calcium phosphate, hypromellose and / or microcrystalline cellulose, croscarmellose sodium and magnesium stearate.

38. (Original) A formulation according to claim 35, wherein core material comprises sumatriptan succinate, calcium carbonate, hypromellose and / or microcrystalline cellulose, croscarmellose sodium and magnesium stearate.

39. (Original) A formulation according to claim 35, which comprises about 20 to 55 % w/w sumatriptan succinate, about 20 to 50 % w/w mannitol or dibasic calcium phosphate or calcium carbonate, about 1 to 10% w/w hypromellose and / or microcrystalline cellulose, about 1 to 5 % w/w croscarmellose sodium and about 0.5 to 2 % w/w magnesium stearate.

40. (Original) A formulation according to claim 39, which comprises about 20 to 55 % w/w sumatriptan succinate, about 20 to 50 % w/w mannitol, about 1 to 10% w/w hypromellose and / or microcrystalline cellulose, about 1 to 5 % w/w croscarmellose sodium and about 0.5 to 2 % w/w magnesium stearate.

41. (Original) A formulation according to claim 39, which comprises about 20 to 55 % w/w sumatriptan succinate, about 20 to 50 % w/w dibasic calcium phosphate, about 1 to 10% w/w

hypromellose and / or microcrystalline cellulose, about 1 to 5 % w/w croscarmellose sodium and about 0.5 to 2 % w/w magnesium stearate.

42. (Original) A formulation according to claim 39, which comprises about 20 to 55 % w/w sumatriptan succinate, about 20 to 50 % w/w calcium carbonate, about 1 to 10% w/w hypromellose and / or microcrystalline cellulose, about 1 to 5 % w/w croscarmellose sodium and about 0.5 to 2 % w/w magnesium stearate.

43-60. (Canceled)

61. (Currently Amended) A method of substantially inhibiting the formation, in a pharmaceutically acceptable oral formulation, of degradation products associated with exposure of a 5-HT-receptor agonist to ambient moisture, which method comprises providing core material comprising a 5-HT-receptor agonist, or a pharmaceutically acceptable salt, solvate or derivative thereof, with a substantially water resistant coating comprising one or more substantially water resistant materials, wherein said one or more substantially water resistant materials comprise one or more waxes, or one or more wax derivatives.

62-79. (Canceled)

80. (Currently Amended) A method of treating a condition prevented, ameliorated or eliminated by administration of a 5-HT-receptor agonist, which method comprises administering to a human patient suffering from or susceptible to such a condition a therapeutically effective amount of a formulation according to ~~any of claims 1 to 42~~ claim 1.

81. (Original) A method according to claim 80, wherein said condition being treated is selected from the group consisting of migraine, cluster headache, chronic paroxysmal

hemicrania, headache associated with vascular disorders, tension headache and paediatric migraine.

82. (Original) A method according to claim 81, wherein said condition is migraine.

83-85. (Canceled)

86. (Currently Amended) A process of preparing a pharmaceutically acceptable oral formulation according to ~~any of claims 1 to 42~~ claim 1, which process comprises providing core material which comprises a therapeutically effective amount of a 5-HT-receptor agonist, or a pharmaceutically acceptable salt, solvate or derivative thereof, and providing the core material with a substantially water resistant coating comprising one or more substantially water resistant materials, wherein said one or more substantially water resistant materials comprise one or more waxes, or one or more wax derivatives.

87. (Original) A process according to claim 86, which employs wet granulation or direct compression techniques.